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Registration Decision RD2015-21

Etoxazole

(publié aussi en français)

30 October 2015

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2015-21E (print version)
H113-25/2015-21E-PDF (PDF version)

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Registration Decision for Etoxazole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Etoxazole Technical and TetraSan 5 WDG Miticide, containing the technical grade active ingredient etoxazole, to control a variety of mites in greenhouse tomatoes and greenhouse ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-15, *Etoxazole*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for etoxazole and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-15. This decision is consistent with the proposed registration decision stated in PRD2015-15.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-15, *Etoxazole* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Etoxazole?

Etoxazole is an active ingredient that regulates mite growth. It does not kill adults, but prevents treated juvenile mites from successfully moulting, and prevents treated eggs from hatching. Treated adult females lay significantly fewer viable eggs. Etoxazole is the active ingredient found in TetraSan 5 WDG Miticide, which is a commercial agricultural product for control of a variety of mites in greenhouse tomatoes and greenhouse ornamentals.

Health Considerations

Can Approved Uses of Etoxazole Affect Human Health?

TetraSan 5 WDG Miticide, containing etoxazole, is unlikely to affect your health when used according to label directions.

Potential exposure to etoxazole may occur through the diet (food and water), when handling and applying the product, or when entering an area that has been treated with the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, the technical grade active ingredient etoxazole was of low acute toxicity by the oral and dermal routes and of slight acute toxicity by inhalation exposure. Etoxazole was non-irritating to the eyes and skin and did not cause an allergic skin reaction. Based on these findings, the signal word and hazard statement "CAUTION – POISON" are required on the label.

The end-use product TetraSan 5 WDG Miticide, containing etoxazole, was of low acute toxicity by the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and skin and did not cause an allergic skin reaction. Based on these findings, no acute hazard labelling is required.

Health effects in animals given repeated doses of etoxazole included effects on the liver and dental abnormalities. Etoxazole did not cause cancer in animals and did not damage genetic material. It did not adversely affect the nervous or immune systems, nor did it affect the ability to reproduce.

When etoxazole was given to pregnant rabbits, minor effects on fetal bone development were observed. These findings occurred at very high doses that also produced toxicity in the mothers. When etoxazole was administered to rats during pregnancy and/or nursing, effects on the juvenile animal (pup deaths) were observed at doses that were not toxic to the mother, suggesting that the young may be more sensitive to etoxazole than the adult animal.

The risk assessment protects against the effects of etoxazole by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Chronic non-cancer dietary intake estimates (food alone) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most etoxazole relative to body weight, are expected to be exposed to less than or equal to 26% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from etoxazole is not of health concern for all population subgroups.

Etoxazole is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of etoxazole is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

MRLs established in Canada for etoxazole may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage.

Occupational Risks From Handling TetraSan 5 WDG Miticide

Occupational risks are not of concern when TetraSan 5 WDG Miticide is used according to the label directions, which include protective measures.

Workers who mix, load or apply TetraSan 5 WDG Miticide can come in direct contact with etoxazole residues via the skin or through inhaling spray mists during application. Furthermore, workers re-entering freshly treated greenhouses can come in direct skin contact with etoxazole residues on treated foliage. Therefore, the label specifies that during mixing, loading, application, clean-up and repair, workers must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves. The label also requires that workers do not enter treated greenhouses for 12 hours after application. Taking into consideration these label statements, the number of applications, and the expectation of the exposure period for handlers and workers, the occupational health risk to these individuals is not expected to be of concern.

For bystanders, exposure from greenhouse use is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Etoxazole Is Introduced Into the Environment?

When used according to label directions, etoxazole does not pose an unacceptable risk to the environment.

When etoxazole is used in accordance with the label and the required risk reduction measures are applied, the resulting environmental risk is considered to be acceptable.

In Canada, etoxazole is used in greenhouses only and, therefore, will not be released directly into the environment. Should etoxazole enter the environment, it is expected to be broken down easily by soil microorganisms. Etoxazole does not mix readily in water and is immobile in soil, and therefore is not expected to move downward through soil and enter groundwater if it were to enter the environment. Etoxazole is not likely to accumulate to a significant level in animal tissue.

Etoxazole is used as a foliar spray for control of pests on greenhouse grown tomato and ornamental plants, and therefore beneficial arthropods and pollinators, which may be used for greenhouse pest management and pollination, could be exposed to spray droplets or residues through contact or oral exposure. Etoxazole presents a negligible acute risk to adult worker bees and adult beneficial arthropods through direct contact or ingestion. Etoxazole may affect immature life stages of certain beneficial arthropods and bees. It is common practice to use adult bumble bees for greenhouse pollination where colonies are not maintained. In some cases, however, growers might choose to maintain honeybee colonies for greenhouse pollination.

Therefore, label statements are required to inform users about the potential risk to immature arthropod and bee life stages, and how to reduce this risk. Etoxazole is toxic to aquatic invertebrates and fish, therefore, label statements prohibiting release of untreated greenhouse effluent directly into aquatic systems will be included.

Value Considerations

What Is the Value of TetraSan 5 WDG Miticide?

Foliar application of TetraSan 5 WDG Miticide controls Lewis mite, twospotted spider mite, carmine mite and European red mite on greenhouse ornamentals and twospotted spider mite and carmine mite on greenhouse tomatoes.

TetraSan 5 WDG Miticide has value for control of spider mites including Lewis mite, twospotted spider mite, carmine mite and European red mite on greenhouse ornamentals, and spider mites including twospotted spider mite and carmine mite on greenhouse tomatoes. Growers have identified etoxazole as a priority for control of mites on greenhouse tomatoes and greenhouse ornamentals. Etoxazole contributes to resistance management because it is a new mode of action for use against spider mites. It could also be a replacement for some registered alternatives which are being phased out, or which have other limitations such as phytotoxicity.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of TetraSan 5 WDG Miticide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with etoxazole residues on the skin or through inhalation of spray mists, anyone mixing, loading and applying TetraSan 5 WDG Miticide must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves. The label also requires that nobody can enter treated greenhouses for 12 hours after application.

Environment

Risk based label statements are required to inform users that etoxazole may affect some species of immature beneficial arthropods. Etoxazole is a mite growth regulator. Based on its mode of action, a precautionary statement regarding potential risk to bee larvae will also be required on the label.

Label statement stating 'toxic to aquatic organisms' is required on the label. In addition, statements to prevent aquatic exposure of etoxazole, by prohibiting release of untreated greenhouse effluent directly into aquatic systems, are required on the label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-15, *Etoxazole)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.